National Institutes of Health
National Heart, Lung, and Blood Institute
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January 6, 2006

Re: Request for Proposals No.: NHLBI-WH-06-09

Dear Ladies and Gentlemen:

The National Heart, Lung, and Blood Institute (NHLBI) invites you to submit a proposal under this Broad Agency Announcement*, NHLBI-WH-06-09, for research of blood samples and clinical data produced by prior WHI clinical trials and observational studies.

Those offerors who believe they have sufficient expertise and resources to conduct such research studies are encouraged to submit a proposal to maximize the scientific yield from the biologic resource and associated participant exposure and outcome data generated by the Women's Health Initiative (WHI) research studies. NHLBI will evaluate proposals received in response to this BAA in accordance with the technical evaluation criteria specified herein through a peer review process.

Proposals will not be evaluated against a specific Government requirement, as in the case of a conventional RFP, as they are not submitted in accordance with a common statement of work. Offerors will develop and submit a Statement of Work with the proposal.

NHLBI anticipates that eight to ten two-year contracts will be awarded for an approximate total of $17.5 million, subject to availability of funds and the Institute priorities at the time of award.

Page and Formatting Limitations

The Technical Plan (objectives, approach, methods and procedures, and schedule) of the Technical Proposal shall not exceed 30 single-sided pages or 15 double-sided pages. This page limitation does not apply to the cover sheet, abstract, table of contents, personnel, facilities, equipment and resources, other considerations, other support, cost information, and literature cited. Appendices shall be limited to 60 single-sided pages or 30 double-sided pages. Pages in excess of this will be deleted and will be neither read nor evaluated. Each page of the Technical Proposal must be numbered sequentially. Offerors are encouraged to limit the overall size of the Technical Proposal, inclusive of appendices, attachments, etc. Note that although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

Type density and size must be 10 to 12 points. If constant spacing is used, 15 cpi (characters per inch) or fewer shall be used, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.

**Authorized by Federal Acquisition Regulation (FAR) 6.102, BAAs are used by federal agencies to fulfill their requirements for scientific study and experimentation that advance the state of the art or increase knowledge and understanding rather than focusing on a specific outcome.*

Offerors are advised to review the following before submitting a proposal:

Part I Contract Schedule
Part II Contract Clauses
Part III List of Documents, Exhibits, and other Attachments
Part IV Representations and Instructions

In addition, offerors are advised to submit a Proposal Intent Response Sheet by March 10, 2006 (see Section J, Attachment 2), and to notify Kim Louth, Contract Specialist, of intent to submit a proposal at the following address:

klouth@nhlbi.nih.gov

Notification to the Contract Specialist of intent to submit a proposal will permit NHLBI to email individual notice of any amendments to the RFP, if any are issued. However, all amendments will be posted on FedBizOpps.
The due date for submittal of proposals is April 7, 2006, 4:00 p.m. (local time). The address for submittal of proposals and packaging instructions is set forth in Part III, Section J, Attachment 1.

This BAA is open to all domestic and foreign sources.

Prospective Offerors are invited to attend a pre-proposal conference on February 27, 2006, from 1:00-3:00 pm, at the Natcher Building on the NIH Campus in Bethesda, Maryland. NHLBI staff will explain the purpose of the initiative, provide instructions about the proposal process and answer questions. Questions provided by February 20, 2006 will be answered at the conference. Offeror institutions are urged to send a representative to this conference. All attendees, as well as anyone who cannot attend the pre-proposal conference, will be given access, through an amendment to the Solicitation, to any distributed materials, questions and answers, and a summary of the discussion. These materials and additional information about the meeting will be posted with the BAA. Attendance is not a pre-requisite for proposal submission and will not be considered a factor in proposal evaluation.

Please direct all questions related to this announcement to my attention.

/s/
Kim Louth, Contract Specialist
Office of Acquisitions
National Heart, Lung, and Blood Institute, NIH

SECTION A - SOLICITATION FORM

1. Purchase Authority: Public Law 92-218 as amended

Request For Proposal (RFP) Number: NHLBI-WH-06-09	3. **Issue Date**: 1-06-2006	4. **Just In Time**: **[ ]** NO **[X]** YES See Part IV Section L	5. **Set Aside**: **[X]** NO **[ ]** YES See Part IV

6. **"Toward Maximizing the Scientific Value of the Biologic Specimens from the Women's Health Initiative"**

ISSUED BY:	SUBMIT OFFERS TO:
Kim Louth, Contract Specialist Office of Acquisitions National Heart Lung & Blood Institute National Institutes of Health 6701 Rockledge Drive, MSC 7902 BETHESDA MD 20892- 7902	See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.

9. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1 until 4:00 p.m. local time on April 7, 2006. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043."

10. THE OFFICIAL POINT OF RECEIPT OF PROPOSALS FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY IS THE ADDRESS PROVIDED FOR THE REVIEW BRANCH AS STATED IN ATTACHMENT 1. IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HER DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE REVIEW BRANCH, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH HHSAR CLAUSE 352.215-70, ENTITLED, "LATE PROPOSALS AND REVISIONS" LOCATED IN SECTION L.1.m. OF THIS SOLICITATION.

11. In accordance with FAR Clause 4.11, Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. **(http://www.ccr.gov)**

12. INFORMATION CALL: Kim Louth, Contract Specialist
PHONE: (301) 435-0712
EMAIL: klouth@nhlbi.nih.gov COLLECT CALLS WILL NOT BE ACCEPTED

TABLE OF RFP CONTENTS

PART I - THE SCHEDULE

*THE CONTRACT SCHEDULE SET FORTH IN SECTIONS B THROUGH H, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS **NOT** AN EXACT REPRESENTATION OF THE PROPOSED CONTRACT DOCUMENT. CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (I.E., THOSE RELATING TO THE ORGANIZATIONAL STRUCTURE [E.G., NON-PROFIT, COMMERCIAL] AND SPECIFIC COST AUTHORIZATIONS UNIQUE TO THE OFFEROR'S PROPOSAL AND REQUIRING CONTRACTING OFFICER PRIOR APPROVAL) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. HOWEVER, THE ENCLOSED CONTRACT SCHEDULE PROVIDES ALL THE NECESSARY INFORMATION FOR THE OFFEROR TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.*

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICE

This BAA seeks proposals to maximize the scientific yield from the biologic resource and associated participant exposure and outcome data in the WHI, by soliciting the best ideas for research studies to apply to the WHI biologic resource. The overall WHI program is intended to improve knowledge about the predictors and prevention of some of the more common diseases affecting older women (cardiovascular diseases, cancers of the breast, colon and rectum, and fractures). Because of their importance to public health, the BAA will expand existing efforts within WHI centered around these diseases. However, extensive information was also collected on other outcomes, such as other cancers, cognition, and functional status, and proposals utilizing these phenotypes or groups of phenotypes will also be considered. NHLBI anticipates that the research programs funded by this BAA will include applications of genomics, proteomics, and other laboratory investigations to the existing frozen samples of DNA, serum, plasma, red blood cells, and urine. This BAA seeks innovative technologies that enable comprehensive yet efficient investigation of sets of markers associated with disease outcomes or treatment effects, or of groups of mediators that might substantively explain the pathway of exposure or treatment effects on disease outcomes. Focused studies on a more limited number of candidate genes or candidate markers will be considered if there are reasonably strong data supporting large effects from these individual markers that need to be confirmed in a large dataset, and their validation has potential public health implications.

Note to the Community:

Investigators can also gain access to the WHI data (including study data not related to the biologic resource) though an established ancillary study mechanism by collaborating with one or more WHI investigators. A portion of the biologic resource not reserved for the BAA is otherwise reserved, and therefore studies that are not suitable or funded through the BAA may be proposed for funding through a variety of other mechanisms. Such ancillary studies are reviewed by the relevant WHI committees and by NHLBI, and if approved can apply for funding from NIH and non-NIH sources outside of the BAA. Procedures for establishing collaboration can be found on http://www.whiscience.org.

ARTICLE B.2. PRICES/COSTS

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be restricted from reimbursement in the resultant contract: 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

ARTICLE B.4. ADVANCE UNDERSTANDINGS
Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK
Contracts awarded as a result of this BAA will incorporate the statement of work proposed by the offeror and negotiated and accepted by the Government. The following information is to assist the offerors in the preparation of their proposals.

a. General Description of the Required Objectives and Desired Results

The laboratory studies done within WHI to date have generally focused on confirming and quantifying individual candidate risk markers for diseases of older women in the observational study, and on explanatory (mechanistic) studies of effect modifiers and mediators in the trials. In general, candidate risk markers in the completed studies were chosen because of promise shown in previous smaller studies, or in studies with less well defined phenotypes. Studies under this BAA will expand on the existing work in regard to validation of risk markers in the observational study and explaining clinical trial findings in the trials of hormone therapy, dietary modification, and calcium/vitamin D.

NHLBI anticipates that some of these studies will apply cutting-edge technologies developed in other programs which are becoming amenable to high throughput investigations, such as those from the fields of genomics, proteomics, and multiplex assays of adipokines and cytokines. However, while the technology needs to pre-exist, the application of the technology to the WHI resource may include both validation of markers found in other studies and discovery of new markers or mechanisms where there is a reasonable basis for suspecting their importance. One model that might conserve the most valuable samples (those from the clinical trials) for the most informative investigations would be the use of the observational study samples for identification and initial validation, before examining the clinical trial samples for confirmation and potential interaction with the trial treatment. Offerors should consider using case-only analyses in the clinical trial components for treatment effects within subsets (e.g., subsets of levels of a biologic variable, or presence or absence of the variable) and for tests of subgroup interactions. Since the randomization fractions within subsets are known, case-only analyses may be more efficient than traditional matched case-control analyses. The case-only approach does not allow for the study of potential risk factors on disease outcome, but such analyses typically have a lower priority in a clinical trial setting than do interactions of intervention effects with baseline factors.

In order to put the resource to the best use, the investigations funded by these awards should not duplicate completed investigations or approved investigations already funded within the WHI, unless there are compelling reasons why replication would be desirable (for example, replication may be necessary for some genomics and proteomics investigations). Offerors should review the information on http://www.whiscience.org for updated information on completed or funded investigations and publications. The WHI CCC will be responsible for publishing and keeping up to date a full list of completed and planned publications and investigations on the study website, and for overall data coordination.

For planning purposes, the website provides dataset documentation (data preparation, created variables, form-level information on demographics, participant characteristics and exposures, and summary tables of frequencies of outcomes in the study populations). The expectation is that the site will provide sufficient information to

write a successful proposal, but the website also provides contact information in the event that limited additional guidance is needed for planning purposes. Alternatively, offerors can choose to include funding for a collaborator or collaborators at the WHI Clinical Coordinating Center (WHI CCC) at the Fred Hutchinson Cancer Research Center (FHCRC) and/or at one or more of the WHI Field Centers to help them develop a proposal and execute the study. Successful awardees will receive assistance from the WHI CCC to select appropriate cases and controls, will receive an initial data set relevant to the selected cases and controls (including basic demographics and number of cases and controls) and will be provided with the biologic samples, at no cost to the awardee. The complete dataset pertinent to the study will be provided after receipt of all laboratory data. In order to protect participant confidentiality, the data set and the biologic samples will be provided under an identification number different from the original study identification number and only a limited number of staff at the WHI CCC will have the link to the original study identification number. Other potential identifiers such as location and dates of clinical events will also be removed. Offerors must sign a data distribution and confidentiality agreement before data and/or samples will be released to them. Awardees will have rights to the data generated under their studies, but will be required to provide an electronic file of the results to the WHI CCC before or upon completion of the award period, and these data will be merged with the WHI dataset for studies within WHI after a reasonable period has elapsed to allow for submission for publication by the awardee. In general, a reasonable period will be six months after the completion of the award period or any no-cost extension negotiated with the Government, unless otherwise agreed to by the Government. Offerors and successful awardees are encouraged but are not required to collaborate with WHI investigators in planning and publishing their studies. Offerors must agree to abide by WHI and NHLBI policies and procedures, including timely submission of manuscripts using WHI data to the WHI Publications and Presentations Committee and the NHLBI for review.

Investigators can also gain access to the WHI data (including study data not related to the biologic resource) through an established ancillary study mechanism by collaborating with one or more WHI investigator. A portion of the biologic resource not reserved for the BAA is otherwise reserved; therefore studies that are not suitable or funded through the BAA may be proposed for funding through a variety of other mechanisms. NHLBI and relevant WHI committees will review such ancillary studies, and, if approved, may be funded from NIH and non-NIH sources outside of the BAA. Procedures for establishing collaboration can be found at http://www.whiscience.org.

Proposals for the BAA should assume that a maximum of the following amounts of biologic materials will be potentially available for distribution among offerors for each study participant at each sampling interval: 1.8 ml serum, 1.8 ml EDTA plasma, I.8 ml citrated plasma, and 50 ug DNA. In exceptional circumstances (e.g, in the case where one or more particularly meritorious proposals would not be able to proceed under these limitations), a larger amount of serum (up to 3.6 ml) and DNA (up to 100 ug) may be made available. The samples to be made available under this BAA will in general only be thawed once (for sub-aliquotting) prior to shipment to the awardees. Blood and urine samples were obtained at baseline and repeated either one year (clinical trial) or three years (observational study) later. In one subset of clinical trial participants additional blood samples were obtained at three yearly intervals, and in another subset of trial and observational study participants' urine samples were obtained at baseline, one year, and every three years in addition to bone mineral density measurements (see below). Lysed red blood cell samples will be available from all study participants at baseline. Note that in a small proportion of study subjects the amount of biologic sample will be smaller, due to their having been used in prior studies or incomplete collections. Parsimonious use of sub-aliquots will be an important factor in the technical evaluation; one way of increasing the scientific yield from a limited resource is to run multiple assays simultaneously on the same sample.

The biologic samples will be returned to the WHI CCC or destroyed at the end of the period of performance, as directed by the NHLBI, unless the awardee obtains agreement from NHLBI to keep the samples for further scientific study.

The proposal should include:

- The hypothesis being tested, if any
- The potential importance of the findings on public health
- Reasons why this cohort is particularly or uniquely suitable for the proposed study
- The number of cases and controls requested for specific outcomes(s)
- Statistical power calculations
- Sample amounts, including steps taken to conserve sample
- Information on sample handling, shipping, and storage
- Ability to perform the laboratory analyses within the period of performance
- A summary of the technology to be used
- Documentation of proficiency with the proposed technology
- Documentation of sensitivity, reproducibility, variability, consistency with external laboratories and standards, sample success rates, locus success rates, as appropriate for the type of technology
- Quality assurance steps to be included in this program
- Documentation of ability to perform statistical analyses of the laboratory findings, or that suitable arrangements for statistical analyses by the WHI CCC (collaboration or subcontract) have been negotiated
- Plans for transmission of an electronic dataset to the WHI CCC within six months of the end of the funding period
- Signed agreement to abide by the policies and procedures for publications of the WHI and the NHLBI
- Agreement to abide by NHLBI policies for data distribution and confidentiality
- Plans for collaboration with WHI investigators, if any
- Data dissemination plan

b. Background Information

Study Population

The WHI study population includes 161,808 postmenopausal women in the United States, 68,132 (42%) of whom were randomized to one or more components of the clinical trial (CT), and 93,676 (58%) of whom were enrolled in the observational study (OS) between 1993 and 1998. Recruitment criteria included being 50-79 years of age, past menopause, and planning to live in the area of a given CC for three years, with specific exclusionary criteria for the DM and HRT Trial components. Specific study goals were set for ethnic distribution (20% minority women in the CT) and age distribution (30% for 50-59 years of age; 45% for 60-69; 25% for 70-79). Table 1 shows the number of participating women by baseline age, race/ethnicity, and participation in CT and OS.

Table 1

Number (and %) of Women by Baseline Age and Race/Ethnicity in the WHI Cohorts

Age	**CT**	**OS**	**Total WHI**
50-54	9,188 (13%)	12,384 (13%)	21,572 (13%)
55-59	14,662 (22%)	17,323 (18%)	31,985 (20%)
60-69	31,394 (46%)	41,199 (44%)	72,593 (45%)
70-79	12,888 (19%)	22,770 (24%)	35,658 (22%)
Race/Ethnicity			
American Indian	292 (<1%)	421 (<1%)	713 (<1%)
Asian	1,519 (2%)	2,671 (3%)	4,190 (3%)
Black	6,983 (10%)	7,635 (8%)	14,618 (9%)
Hispanic	2,875 (4%)	3,609 (4%)	6,484 (4%)
White	55,525 (81%)	78,016 (83%)	133,544 (83%)
Unknown	938 (1%)	1,324 (1%)	2,262 (1%)
Total	**68,132**	**93,676**	**161,808**

As described above, the CT involves three randomized intervention comparisons in a partial factorial design. The numbers of women in the hormone therapy (HT), dietary modification (DM) and calcium/vitamin D (CaD) components of the CT are 27,347, 48,835 and 36,282 respectively. Of the women in the HT component 10,739 (39%) were post-hysterectomy at baseline. These women were assigned on a 1-1 basis to 0.625 mg/day conjugated equine estrogen (CEE) or placebo, while the remaining 16,608 (61%) of HT women were randomly assigned to this same estrogen preparation plus 2.5 mg/day medroxyprogesterone acetate (CEE+MPA) or placebo. The women enrolled in the DM component were assigned to a low-fat eating pattern, high in vegetables, fruits and grains, intervention (40%) or control (60%), while women in the CaD component were assigned with equal probabilities to 1,000 mg/day calcium carbonate plus 400 international units/day of vitamin D or placebo. Table 2 shows the number of women by baseline age and by race/ethnicity for each of the CT components. Baseline characteristics of the CT and OS cohorts, and published study results, can be found at http://www.whiscience.org**.**

Table 2

Number (%) of Women by Baseline Age and Race/Ethnicity in the CT

	HT	DM	CaD
Age	**Intervention + Placebo**	**Intervention + Control**	**Intervention + Placebo**
50-54	3,425 (13%)	6,961 (14%)	5,153 (14%)
55-59	5,407 (20%)	11,039 (23%)	8,270 (23%)
60-69	12,365 (45%)	22,715 (47%)	16,521 (46%)
70-79	6,150 (22%)	8,118 (17%)	6,338 (17%)
Race/Ethnicity			
American Indian	130 (<1%)	202 (<1%)	149 (<1%)
Asian	527 (2%)	1,105 (2%)	721 (2%)
Black	2,738 (10%)	5,262 (11%)	3,315 (9%)
Hispanic	1,537 (6%)	1,845 (4%)	1,502 (4%)
White	21,994 (80%)	39,762 (81%)	30,155 (83%)
Unknown	385 (1%)	659 (1%)	440 (1%)
Total	**27,347**	**48,835**	**36,282**

By virtue of the partial factorial design, some women participated in more than one trial component. The proportions of women who participated in more than one CT component are shown in Table 3.

Table 3

Proportions of Participants in More Than One CT Component

CT Component	Total Number	Also in HT	Also in DM	Also in CaD	Also in DM + CaD	Also in HT + CaD	Also in DM + HT
DM	48,835	16.5 %	--	51.6%	--	10.3%	--
HT	27,347	--	29.4 %	58.8%	18.4%	--	--
CaD	36,282	44.3 %	69.5 %	--	--	--	13.8%

Overview of Data Collection

Women in the CT and OS provided extensive information on characteristics and exposures at baseline and during follow-up. Blood specimens were collected, separated and stored at baseline, and at one year from randomization for CT women and at baseline and three years from enrollment for OS women. The biologic specimen resource will be described in greater detail below.

Similar baseline questionnaire data were collected for CT and OS women, and includes medical and family health history, reproductive history, behavioral habits and history (several questionnaires), and food frequencies. Baseline data also include interviewer-administered hormone use data, extensive data on "current" medications and supplements, as well as physical and functional measurements. Clinical breast exams, mammograms, and ECGs were also required at baseline in the CT. The OS and CT components each had additional specialized data collection at baseline. The protocol, procedures, data collection forms, and dataset documentation can be found at http://www.whiscience.org.

Much of the information collected at baseline was repeated or updated at selected follow-up times with rather comprehensive data and specimen collection at one year from randomization in the CT and at three years from enrollment in the OS. Core items and specialized exposure information was collected each year in the OS and a comprehensive set of exposures was updated every three years. Certain sub-cohorts provide more extensive information during study follow-up. Bone density measurements and urine specimens were collected at baseline, and at years 1, 3, 6 and 9 on CT and OS women seen at the three Bone Mineral Density Clinical Centers. The WHI protocol at http://www.whiscience.org provides additional detail on the nature and frequency of the collection of data and specimens in the WHI. The WHI dataset also includes measurements on certain core analytes on subsamples of the CT and OS women at baseline and during follow-up (see below). Data from various WHI ancillary studies are also to be made available for merging with the WHI dataset as a condition of ancillary study approval. Clinical outcome data collected biannually in the CT and annually in the OS, on a broad range of disease categories, constitute a most important aspect of the WHI dataset. Self-reports of outcomes are recorded, and a physician adjudicates all hospitalizations locally, while key outcome events are also centrally adjudicated. Further detail on the outcome ascertainment process and on the number of events through 2004 will be provided below.

Biological Samples

Blood samples were to be collected on all CT participants at baseline and year 1 and on all OS participants at baseline and year 3. Fasting bloods were collected with minimal stasis into royal blue (serum), light blue (citrate), and lavender (EDTA) tubes and separated in a refrigerated centrifuge at a RCF of 1,300 g for 10 minutes. Aliquots were stored at -70 degrees Celsius within two hours of collection. Additional blood samples were collected from a 6% subsample of CT participants at years 3, 6, and 9, for analyses of "core analytes." A 1% subsample of OS women was randomly selected to provide additional blood samples at baseline. As in the CT, this substudy also oversampled minority women. The core analytes included micronutrients (carotenoids and tocopherols); lipid fractions (triglycerides, total cholesterol, LDL-C, HDL-C, HDL-2, HDL-3, Lp(a); clotting factors (Factor VII Ag, Factor VIIC, fibrinogen); glucose and insulin.

The 6% subsample in the CT included a six-fold oversampling of racial/ethnic minority women while retaining a 6% subsampling in each CC. It also included a two-fold oversampling of HT (including HT and DM overlap) women (8.6%) as compared to DM-only women (4.3%). The numbers of CT subsample women by racial/ethnic group and CT component are shown in Table 4.

Table 4

Ethnicity of Participants in 6% CT Subsample

Race/Ethnicity	**HT only**	**DM only**	**HT and DM**	**Total N**	**%**
American Indian/ Alaska Native	45	57	18	120	2.6
Asian/Pacific Islander	140	161	36	337	7.4
Black/African American	394	504	302	1,200	26.4
Hispanic	261	167	148	576	12.7
White	850	929	447	2,226	48.9
Unknown	38	34	21	93	2.0
TOTAL	**1,728**	**1,852**	**972**	**4,552**	**100**

The number of biologic samples of each type by sampling period is shown in Table 5.

Table 5

Number and Timing of Blood Samples

Cohort	Time	# specimen collected
		Serum and plasma
CT	Baseline	68,135
	Year 1	62,735
	Year 3	3,926
	Year 6	3,530
	Year 9	3,250
OS	Baseline	93,676
	Year 3	75,000
		RBC
CT	Baseline	68,135
		DNA
CT		68,135
OS		93,676
		Urine (3 BD CCs)
CT	Baseline	5,390
	Year 1	4,460
	Year 3	3,670
	Year 6	3,000
	Year 9	2,500
OS	Baseline	7,225
	Year 3	5,930
	Year 9	4,500

Retention and Adherence

In WHI, retention is defined as maintaining contact with the participant for collection of outcome data. All CT participants are asked to complete a Medical History Update (Form 33, F33) semi-annually (annually for OS, below)for outcomes data collection. CT participants who do not complete a F33 for more than eighteen months and

have no other contact with the clinic for six months are considered lost-to-follow-up. OS participants are considered lost-to-follow-up after twenty-four months without a F33. Women known to be alive, but without a F33 in the last 18 months (CT) or 24 months (OS), are classified as "Alive/Lapsed participation". Women who request no further routine contacts are classified as "Stopped follow-up" because their morbidity status is not known.

Table 6 shows the percentage of participants in each of these follow-up categories in each study component as of 9/12/05. The average length of follow-up (in months) for each component (in parentheses) at the time these data were reported was 97.0 (DM), 94.5 (HT), 84.4 (CaD), and 90.9 (OS). Lost to follow-up and stopped follow-up rates are low and when combined compare favorably to the overall design assumption of 1.5% per year of follow-up. National Death Index searches are run on these last categories at regular intervals, and hence the vital status of virtually all participants is known.

Table 6

Retention of Participants:
Follow-up Status by Study Component as of September 12, 2005

Follow-up status	DM	HT	CaD	OS
Alive/Current participation	90.3	89.7	90.0	83.4
Alive/Lapsed participation	0.5	0.5	3.1	5.2
Stopped follow-up	3.2	3.7	1.9	2.5
Lost to follow-up	1.1	1.2	0.7	2.2
Deceased	4.9	6.0	4.3	6.7

Details of adherence to study interventions, and trial results, can be found in the primary trial publications referenced on http://www.whiscience.org.

Outcomes Reporting in the WHI CT and OS

Most outcomes in the WHI were initially ascertained by self-report. Women in the CT were asked to complete a medical history update every six months, as were OS women annually. Participants reporting an outcome requiring documentation were asked to complete a more detailed form that includes the information needed to request the associated medical records. Clinical center staff assembled hospital and related records, and the local physician adjudicator evaluated and classifies charts having potential cardiovascular, cancer, or fracture outcomes. All deaths were also locally classified. Other outcomes, for example diabetes and gall bladder disease were collected as self-reports only. A central committee further adjudicated key cardiovascular outcomes. Hip fractures and selected cancers (breast, colon, rectum, ovary, endometrium) were also centrally reviewed using standardized procedures. The agreement rates between local and central adjudicators were 80-95% for specific cardiovascular outcomes and 90-100% for hip fractures and specific cancer outcomes.

Table 7 shows the number of adjudicated events in the CT, OS, and combined CT and OS through September 12, 2005, for selected outcome categories, including the designated primary and secondary clinical outcomes in the CT. Outcomes will continue to be collected, and hence up to two years' worth of additional outcomes data will be available at the time of commencing investigations funded by this BAA (please see www.whiscience.org for updated numbers). Table 8 provides corresponding counts for selected self-report outcomes. Table 9 provides counts for adjudicated events by CT component. Outcome data by age group and by race/ethnicity can be found at http://www.whiscience.org, as can counts for some additional outcome categories. Counts for locally confirmed, less frequent, cancers are shown in Table 10.

Table 7

Centrally Confirmed Outcomes in the CT and OS for Selected Outcome Categories as of September 12, 2005

Outcomes	**CT**	**OS**	**CT + OS**
Coronary Heart Disease (MI and CHD death)	2,198	2,471	4,669
Angina	2,412	2,837	5,249
CABG/PTCA	2,740	3,136	5,876
Carotid Artery Disease	461	574	1,035
Congestive Heart Failure	1,743	2,305	4,048
Stroke	1,589	2,011	3,600
Peripheral Vascular Disease	410	526	936
Coronary Disease [+]	5,925	6,766	12,691
Total Cardiovascular Disease	**7,720**	**9,232**	**16,952**
Breast Cancer	2,790	4,106	6,896
Invasive Breast Cancer	2,242	3,426	5,668
Ovary Cancer	239	362	601
Endometrial Cancer	372	551	923
Colorectal Cancer	722	908	1630
Other Cancer	2,970	4,061	7,031
Total Cancer	**6,789**	**9,516**	**16,305**
Hip Fracture	791	1,132	1,923
Vertebral Fracture	828	123*	951
Other Fracture	7,691	697*	8,388
Total Fracture	**8,848**	**1,878**	**10,726**
Cardiovascular Deaths	1,113	1,802	2,915
Cancer Deaths	1,627	2,654	4,281
Total Deaths	**3,605**	**6,260**	**9,865**

[+] Includes clinical MI, CHD death, definite and possible evolving Q wave MI (silent MI), angina, congestive heart failure, and CABG/PTCA

* Only adjudicated in a subsample.

Table 8

Self-Reported Outcomes in the CT and OS for Selected Outcome Categories in Participants who did not Report a Prevalent Condition at Baseline as of September 12, 2005

Outcomes	**CT**	**OS**	**CT +OS**
Deep Vein Thrombosis (inpatient only)	803	762	1,565
Pulmonary Embolism	511	480	991
Diabetes (treated)	5,264	5,079	10,343
Gallbladder Disease	5,248	5,690	10,938
Hysterectomy	2,075	3,440	5,415
Glaucoma	7,565	8,516	16,081
Osteoporosis	14,695	20,767	35,462
Osteoarthritis	13,026	15,619	28,645
Rheumatoid Arthritis	4,009	4,607	8,616
Intestinal Polyps	10,620	13,183	23,803
Lupus	732	1,001	1,733
Kidney Stones	1,877	2,327	4,204
Cataracts	21,568	27,208	48,776
Treated Hypertension	17,885	21,589	39,474

Table 9
Centrally Confirmed Outcomes in the CT and OS for
Selected Outcome Categories as of September 12, 2005

	HT		DM	CaD
Outcome	**CEE**	**CEE+MPA**		
Coronary Heart Disease (MI and CHD death)	492	555	1429	982
Angina	570	515	1629	1114
CABG/PTCA	593	663	1830	1281
Carotid Artery Disease	117	104	292	219
Congestive Heart Failure	421	383	1,167	801
Stroke	321	409	1071	744
Peripheral Vascular Disease	95	111	261	196
Deep Vein Thrombosis	159	248	Self-report only	Self-report only
Pulmonary Embolism	107	179	Self-report only	Self-report only
DVT/PE	222	336	Self-report only	Self-report only
Coronary Disease	1,321	1,390	3,969	2,770
Total Cardiovascular Disease	**1,856**	**2,111**	**5,161**	**3,637**
Breast Cancer	316	625	2,150	1,369
Invasive Breast Cancer	260	498	1,727	1,087
Ovary Cancer	20	59	182	125
Endometrial Cancer	0	96	305	184
Colorectal Cancer	136	189	506	339
Other Cancer	501	769	2,068	1,399
Total Cancer	**944**	**1,653**	**4,986**	**3,289**
Hip Fracture	142	239	500	374
Vertebral Fracture	137	227	552	378
Other Fracture	1,266	2,002	5,340	3,712
Total Fracture	**1,462**	**2,327**	**6,095**	**4,260**
Cardiovascular Deaths	258	277	715	470
Cancer Deaths	302	411	1,126	726
Total Deaths	**727**	**918**	**2,404**	**1,551**

Table 10

Locally Confirmed Outcomes in the CT and OS for Selected Cancers as of September 12, 2005

Cancer Category	CT	OS	CT + OS
Bladder	176	218	394
Brain	79	87	166
Cervix	51	44	95
Esophagus	34	37	61
Kidney	136	182	318
Leukemia	139	185	324
Lung	593	772	1,365
Lymphoma, Non-Hodgkin's	265	380	645
Melanoma of skin	400	510	910
Multiple Myeloma	106	96	202
Pancreas	146	186	332
Stomach	45	56	101
Thyroid	90	106	196

c. Reference Material

Offerors should review the information on http://www.whiscience.org for publications and materials describing the WHI program, its findings, and updated information on completed or funded investigations. The website also provides detailed information on participant demographics, other participant characteristics, and frequencies of outcomes.

d. Level of Funding

Appropriated funds are anticipated to be available for this BAA in the total amount of $17.5 million over FY 2007-2008. NHLBI expects to award eight to ten contracts for a two-year period of performance.

e. Timeline

Offerors should propose a timeline for starting and completing the laboratory phase, for starting and completing the statistical analysis, for submission of the data to the WHI CCC, and for publication of the results. The timeline should assume that it may take up to three months for the WHI CCC to assemble the required data set of cases and suitable controls and to pull, aliquot, and ship serum or plasma samples. DNA samples for CHD, stroke, breast cancer, colorectal cancer, and hip fractures and suitable controls will in general already have been extracted and aliquots prepared, and may be shipped within two months. DNA samples for other outcomes may take up to six months to extract, aliquot, and ship.

f. Clinical Research/Human Subjects

This project does not focus on clinical research of human subjects. Research will involve the study of existing data, documents, records, or specimens. This information is recorded by the Principal Investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. In accordance with NIH policies, IRB approval or waiver is required.

The WHI CCC will seek approval of all awarded investigations from the IRB of the Fred Hutchinson Cancer Research Center.

g. Special Requirements

1. GOVERNMENT FURNISHED MATERIAL/FACILITIES AND GOVERNMENT PROPERTY

The WHI CCC will provide a dataset of cases and suitable controls, and will provide the plasma, serum, urine, and DNA samples at no cost to the awardees. Materials provided are to be used for no purpose other than that stated in the awarded contract.

Offerors should assume that it may take up to three months for the WHI CCC to assemble the required data set of cases and suitable controls and to pull, aliquot, and ship serum or plasma samples. DNA samples for CHD, stroke, breast cancer, colorectal cancer, and hip fractures and suitable controls may be shipped within two months. DNA samples for other outcomes may take up to 6 months to extract, aliquot, and ship.

Offerors are expected to have the necessary equipment to carry out the proposed studies.

2. DATA, DATA RIGHTS, PATENTS, COPYRIGHTS

All data collected or developed in the performance of this program will remain in the contractor's possession. However, all contractors will be required to make their data readily available to the general scientific community. Wide dissemination of the data will be made by publication in scientific journals, presentations at study-sponsored and national scientific meetings, and a study web site. A Dissemination Plan will be part of the initial proposal and regular updates will be required in the deliverables.

It is expected that contractors will apply for copyrights and patents on data collected and developed in the performance of this program. Contractors will be required to include in their annual technical reports full disclosure of intent to file patent applications and actual filings on materials, reagents, animal models or procedures derived or established, whether in the US or outside the US. They will also be required to fully disclose any efforts to transfer their technology or receipt of support from outside entities interested in future access, partnering, or license to the developing technologies.

3. REPLICATION, DISSEMINATION, OR USE OF THE RESULTS

The results shall be provided to the WHI CCC at the end of the contract period. Results may be made available to other investigators six months after the end of the contract period. The contractors will have the rights to use of their data, but will be required to share them as noted above. The primary method of dissemination will be through scientific publications and presentations. The contractors will be required to adhere to the publications and presentations policies of the WHI program. The data from the studies under this BAA will be included in the limited access datasets in accordance with the NHLBI Limited Access Data Clause and the NHLBI Policy for Distribution of Data and future modifications thereof.

4. INFORMATION TECHNOLOGIES

The proposal shall include adequate plans to back up the data generated under the contract.

ARTICLE C.2. REPORTING REQUIREMENTS
In addition to those reports required by other terms of the contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with ARTICLE F.1. DELIVERIES of this contract:

1. Program Plan
A Final Protocol, Manual of Operating Procedures, and Program Plan shall be submitted thirty days after contract award for review and approval. The plan shall identify technical risks and critical decision points that are expected to result, and include a one page graphic that reflects, task-by-task, when the key milestones of the contract work will be met. All revisions to the approved plan shall be submitted to the NHLBI for review and approval.

2. Abstracts and Manuscripts
Abstracts and Manuscripts in progress and proposed for publication shall be provided in accordance with the WHI Publications and Presentations Policy (http://www.whiscience.org).

3. Interim Progress Reports
This semi-annual report shall document and summarize all work results for the previous six-month period. This report shall be in sufficient detail to explain comprehensively the results achieved. The report should be in letter form (2-3 pages) to both the Contracting and Project Officers. The report should include progress for the elapsed six months, problems encountered during the period, a discussion of milestones met or missed, a summary of activities planned for the next six months, and manuscripts in progress, submitted, or published.
The first reporting period consists of the first full six months of performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of six full calendar months. An Interim Progress Report is not required for periods in which an annual or final report is due.

4. Annual Technical Reports
This report shall document and summarize all work results for the period covered. Specifically, the report shall include:

Face page to include contract number, title, period of performance being reported, Contractor's name and address, telephone and facsimile numbers, and date of submission.

An executive summary, to include:

A statement of intended work for the reporting period;
A brief overview of the work that was completed for the reporting period;
A brief overview of any problems (technical or financial) that occurred during the reporting period and their resolution or status;
The advancements made in any of the technical tasks and/or milestones set forth in the statement of work;
An update to the Program Plan;
A summary of activities planned for the next reporting period;
A full description of data pertaining to:
- --The work performed during the reporting period;
- --The materials and methods pertaining to the work;
- --The relationship between the accomplishments made relative to the goals, objectives, and milestones of the statement of work; and
- --Problems encountered and their resolution.

Copies of manuscripts (published or unpublished) derived from research under the contract and copies of all abstracts, manuscripts, preprints and publications that resulted from work conducted or any protocol or method developed specifically under this contract during the performance period;
Manuscripts and publications resulting from this work must cite the support received from this award;
An update of the Dissemination Plan, including time line and discussion of dissemination made to date;
Full disclosure of intent to file patent applications in the U.S. or outside of the U.S. on materials, animal models, or procedures derived or established by the work supported under this contract;
Full disclosure of patent applications filed in the U.S. or outside of the U.S. as well as copies of patent applications;
Full disclosure of any efforts to transfer the technology or receipt of support from outside entities interested in future access, partnering, or license to the developing technologies.

5. Final Technical Report

This report shall consist of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved, and the final Dissemination Plan including dissemination to date. The final report shall be submitted on or before the last day of the contract performance period.

6. Summary of Salient Results

The Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This report will be required on or before the expiration date of the contract.

7. Other Reports

1. Subset Differences, if applicable
   Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups as approved by the IRB, and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

2. Invention Reporting Requirement
   All reports and documentation required by [FAR Clause 52.227-11/FAR Clause 52.227-11 (Deviation)/FAR Clause 52.227-13] including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040 A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the expiration date of the contract to the Contracting Officer.

The annual utilization report shall be submitted in accordance with ARTICLE F.2. DELIVERIES of this contract to:

Contracting Officer
National Institutes of Health
NHLBI, Office of Acquisitions
6701 Rockledge Drive, RKL II, Room 6222
Bethesda, Maryland 20892 -7902

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH.

SECTION D - PACKAGING, MARKING AND SHIPPING

The contractor shall guarantee all deliverables required under this contract to be packaged, marked, and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and contractor name. The contractor shall guarantee that all required materials be delivered in immediate usable and acceptance condition.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, the Project Officer is the authorized representative of the Contracting Officer. Inspection and acceptance will be performed at:

Project Officer (PO) NHLBI/NIH
Two Rockledge Center, MSC 7935
6701 Rockledge Drive, Suite 8204
Bethesda, MD 20892-7935 (Courier service zip 20817)

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within thirty days of receipt.

The Government reserves the right to an Inspection period of thirty calendar days, unless a different time period is stated when (the Record of Call/elsewhere in the contract). The receiving report, completed and signed by the appropriate official, constitutes acceptance and shall be acknowledged to the payment office (OFM).

c. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause No. 52.246-9, INSPECTION OF RESEARCH AND DEVELOPMENT (Short Form) (April 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE
The period of performance for this contract shall be from January 15, 2007, through January 14, 2009.

ARTICLE F.2. DELIVERABLES
Satisfactory performance of the contract shall be deemed to occur upon performance of the work described in ARTICLE C.1., and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule.

A. The items specified below, as described in SECTION C, ARTICLE C.2., will be required to be delivered F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. Destination, within Consignees Premises (APRIL 1984), and in accordance with and by the dates specified below:

Item	Description	Quantity/Individual	Delivery Schedule
a.	Final Protocol Final Manual of Operations Program Plan	1-CO 1-PO	February 14, 2007
b.	Semi-Annual Progress Reports	1-CO 1-PO	July 30, 2007 July 30, 2008
c.	Annual Technical Report	1-CO 1-PO	February 14, 2008
d.	Final Report	1-CO 1-PO	February 14, 2009
e.	Final CD-ROM or DVD-ROM and documentation	1-CO 1-PO 1-WHI CCC	February14, 2009
f.	Biological Specimens	As directed by the PO	February 14, 2009

PO = Project Officer CO = Contracting Officer CCC = Clinical Coordinating Center

B. The items in ARTICLE F.1.A above shall be addressed and delivered as follows:

ADDRESSEES
Project Officer (PO) NHLBI/NIH
Two Rockledge Center, MSC 7935
6701 Rockledge Drive, Suite 8204
Bethesda, MD 20892-7935 (Courier service zip 20817)

Contracting Officer (CO) NHLBI/NIH
Two Rockledge Center, MSC 7902
6701 Rockledge Drive, Room 6222
Bethesda, MD 20892-7936 (Courier service zip 20817)

For electronic data deliveries only:

WHI Clinical Coordinating Center
Fred Hutchinson Cancer Research Center
1212 Aloha M3-A410
Seattle, WA 98109

ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)
This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with **Alternate I** (April 1984).

52.242-17, Government Delay of Work (April 1984)

SECTION G - CONTRACT ADMINISTRATION DATA

Any contract awarded from this RFP will contain the following:

ARTICLE G.1. PROJECT OFFICER
The following Project Officer(s) will represent the Government for the purpose of this contract:

[To be specified prior to award]

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

[The Contracting Officer hereby delegates the Project Officer as the Contracting Officer's authorized representative responsible for signing software license agreements issued as a result of this contract.]

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL

The personnel specified in this contract are considered to be essential to the work to be performed hereunder. Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written consent of the Contracting Officer; provided, that the Contracting Officer may ratify in writing such diversion and such ratification shall constitute the consent of the Contracting Officer required by this article. The contract may be amended from time to time during the course of the contract to either add or delete personnel, as appropriate.

The following individuals are considered to be essential to the work being performed hereunder:

NAME	TITLE
[To be specified prior to award]	

ARTICLE G. 3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST

a. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts NIH(RC)-1 are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

(1) Invoices/financing requests shall be submitted as follows:

(a) To be considered a "proper" invoice in accordance with FAR 32.9, Prompt Payment, each invoice shall clearly identify the two contract numbers that appear on the face page of the contract as follows:

Contract No. (This is the 17 digit number that appears in Block 2 of the SF-26, i.e. HHSN261200411000C.)

ADB Contract No. (This is the 10 digit number that appears in the upper left hand corner of the SF-26, i.e. N01-CO-41234.)

(b) An original and two copies to the following designated billing office:

Contracting Officer
Office of Acquisitions
National Heart, Lung, and Blood Institute, NIH
Rockledge Building (RKL II), Room 6222
6107 Rockledge Drive, MSC 7902
BETHESDA MD 20892- 7902

(2) Inquiries regarding payment of invoices should be directed to the designated billing office, (301)435-0340.

ARTICLE G.4. CONTRACT FINANCIAL REPORT

a. Financial reports on the attached Form NIH 2706, Financial Report of Individual Project/Contract, shall be submitted by the Contractor in accordance with the Instructions for Completing Form NIH 2706, which accompany the form, in an original and two copies, not later than the 30th working day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are listed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. Unless otherwise stated in that part of the Instructions for Completing Form NIH 2706, entitled "**PREPARATION INSTRUCTIONS**," all columns A through J, shall be completed for each report submitted.

c. The first financial report shall cover the period consisting of the (FIRST FULL CALENDAR MONTH/FIRST FULL THREE CALENDAR MONTHS) following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a (monthly/quarterly) basis.

d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

e. The listing of expenditure categories to be reported will be developed before award.

f. The Government may unilaterally revise the NIH 2706 to reflect the allotment of additional funds.

ARTICLE G.5. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7(d)(2), "Allowable Cost and Payment" incorporated by reference in this contract in Part II, Section I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Contracts Management
National Institutes of Health
6100 Building, Room 6B05
6100 EXECUTIVE BLVD MSC 7540
BETHESDA MD 20892-7540

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.6. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the DHHS Publication (OS) 686, entitled, **Contractor's Guide for Control of Government Property**, (1990) which can be found at:

http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm

ARTICLE G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluations will be prepared annually to coincide with the anniversary date of the contract.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://oamp.od.nih.gov/OD/CPS/cps.asp

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. The information below is a summary of the NIH Policy Announcement:

The contractor shall maintain the following information: (1) a list of the names and titles of the Principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

ARTICLE H.2. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.3. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

All uses of WHI biologic materials will be reviewed centrally by the Fred Hutchinson Cancer Research Center IRB under the waiver of informed consent procedure. As noted on http://www.whiscience.org, the Clinical Coordinating Center will assist offerers in obtaining IRB approval. In addition to the central review, offerors need to comply with any local requirements.

ARTICLE H. 4. RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (Including Human Gene Transfer Research)

All research involving Recombinant DNA Molecules shall be conducted in accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html) and the May 28, 2002 Notice, Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html) (and any subsequent revisions to the Guide Notice) which stipulates biosafety and containment measures for recombinant DNA research and delineates critical, ethical principles and key safety reporting requirements for human gene transfer research (See Appendix M of the Guidelines). These guidelines apply to both basic and clinical research studies.

The Recombinant DNA Advisory Committee (RAC) is charged with the safety of manipulation of genetic material through the use of recombinant DNA techniques. Prior to beginning any clinical trials involving the transfer of recombinant DNA to humans, the trial must be registered with the RAC. If this contract involves new protocols that contain unique and//or novel issues, the RAC must discuss them in a public forum and then the Institutional Biosafety Committee (IBC), the Institutional Review Board (IRB), and the project officer and contracting officer must approve the protocol prior to the start of the research.

Failure to comply with these requirements may result in suspension, limitation, or termination of the contract for any work related to Recombinant DNA Research or a requirement for contracting officer prior approval of any or all Recombinant DNA projects under this contract. This includes the requirements of the Standing Institutional Biosafety Committee (IBC) (See http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm).

As specified in Appendix M-1-C-4 of the NIH Guidelines, any serious adverse event must be reported immediately to the IRB, the IBC, the Office for Human Research Protections (if applicable), and the NIH Office for Biotechnology Activities (OBA), followed by the filing of a written report with each office/group and copies to the project officer and contracting officer. (http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm#_Toc7255836).

ARTICLE H.5. HUMAN EMBRYONIC GERM CELL (HEGC) RESEARCH

All HPSCRUG (Human Pluripotent Stem Cell Review Group) approved research involving human embryonic germ cells shall be conducted in accordance with the NIH Guidelines for Research Using Human Pluripotent Stem Cells (http://stemcells.nih.gov/policy/guidelines.asp)

ARTICLE H.6. HUMAN EMBRYONIC GERM CELL (HEGC) RESEARCH

Federally funded research involving the use of human embryonic germ cells derived from fetal tissue shall not be conducted under this contract until Human Pluripotent Stem Cell Review Group (HPSCRG) review and approval has been obtained. Once approved by the HPSCRG, all research shall be conducted in accordance with the NIH Guidelines for Research Using Human Pluripotent Stem Cells (http://stemcells.nih.gov/policy/guidelines.asp).

ARTICLE H.7. HUMAN EMBRYONIC STEM CELL (HESC) RESEARCH

All research conducted under this contract shall involve the use of existing human embryonic stem cells established under the NIH Embryonic Stem Cell Registry only.

ARTICLE H.8. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

a. Pursuant to Public Law(s) cited in paragraph b. , below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded,

or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.9. NEEDLE EXCHANGE

a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[Applicable information to be included at award]

ARTICLE H.10. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

(1) The Small Business Subcontracting Plan, SECTION J, Attachment , attached hereto and made a part of this contract.

(2) The failure of any contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. Subcontracting Reports

(1) The contractor shall submit the Subcontracting Report for Individual Contracts, SF-294 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract: **April 30th, October 30th**

The Report shall be shall be submitted via: http://www.esrs.gov

(2) The contractor shall submit the Summary Subcontract Report, SF-295 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. The Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract: **October 30th**

The first Report shall be submitted after the first full year of this contract in addition to any fractional part of the year in which this contract became effective. The Report shall be submitted via: http://www.esrs.gov .

ARTICLE H.11. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to the P.L.(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown or the applicable Executive Level for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as "indirect costs" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The per year salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

b.

Public Law No.	**Fiscal Year**	**Dollar Amount of Salary Limitation***

[Applicable information to be included at award]

ARTICLE H. 12. PUBLICATION AND PUBLICITY

The contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with federal funds from the National Heart, Lung and Blood Institute, National Institutes of Health, Department of Health and Human Services, under Contract No. .

ARTICLE H.13. PRESS RELEASES

a. Pursuant to Public Law(s) cited in paragraph b., below, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

b.

Public Law and Section No.	**Fiscal Year**	**Period Covered**

[Applicable information to be included at award]

ARTICLE H.14. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS** (**1-800-447-8477).** All telephone calls will be handled

confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.15. ANTI -LOBBYING

a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall only be used for normal and recognized executive-legislative relationships. Contract funds shall not be used, for publicity or propaganda purposes; or for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.

b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Public Law and Section No.	**Fiscal Year**	**Period Covered**

[Applicable information to be included at award]

ARTICLE H.16. LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES

a. Pursuant to Public Laws(s) cited in paragraph b., above, contract funds shall not be used to support activities that promote the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act (21 U.S.C. 812). This limitation shall not apply when the contractor makes known to the contracting officer that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

b.

Public Law and Section No.	**Fiscal Year**	**Period Covered**

[Applicable information to be included at award]

ARTICLE H.17. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at : http://ott.od.nih.gov/NewPages/64FR72090.pdf. is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

Note: For the purposes of this Article, the terms, "research tools," "research materials," and "research resources" are used interchangeably and have the same meaning.

ARTICLE H.18. SHARING RESEARCH DATA

The contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

ARTICLE H. 19. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

ARTICLE H.20. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

The Policy requests that beginning May 2, 2005, NIH-funded investigators submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html.

ARTICLE H.21. GOVERNMENT CONTROL OVER UNDELIVERED AND/OR UNPUBLISHED RECORDS AND DATA

(a) As used in this clause, "records and data" means: (1) any handwritten, typed, or printed documents (including, but not limited to, memoranda, letters, writings, books, brochures, transcripts, minutes, electronic transmissions, study findings, laboratory note books, chromatograms, spectra, and maps); (2) documentary material in other forms (such as punchcards, magnetic or paper tapes, instrumentation cards, computer discs, electronically stored information, audio or video recordings, motion pictures, photographs, slides, microfilm, and microfiche); and, (3) biological samples and pathology materials (pathology slides, paraffin blocks, and wet tissues). Records and data may or may not constitute a specific deliverable defined under the terms of the contract.

(b) The purpose of this clause is to define the Government's control over records and data that are produced by the

Contractor under this contract, but are not defined as a deliverable under the terms of the contract, or are not yet in the Government's physical possession if a deliverable under the terms of the contract. This clause is designed to serve public policy by limiting the disclosure of certain records and data if disclosure is made at a time when such records and data remain unvalidated and unreliable (i.e. may not have undergone a quality control nor subsequent audit and inspection as part of a quality assurance process) and could thereby lead to erroneous conclusions which might threaten public health or safety.

(c) The Government shall be deemed as having no control over, or direct ownership of records and data created or produced by the Contractor in the performance of this contract until such time as the records and data have been: subjected to an acceptable method of quality control and quality assurance; (2) delivered to the Government or obtained by the Government under the terms of this contract; (3) published in accordance with the terms of this contract; or (4) used by the Federal Government in developing an agency action that has the force and effect of law.

(d) In the event of a contract termination, this clause does not relieve the contractor of its obligations set forth elsewhere in this contract to transfer title and deliver to the Government work in process, completed work, supplies, and other material produced or acquired for the work terminated, or, the completed or partially completed plans, drawings, information, and other property that, if the contract had been completed, would be required to be furnished to the Government.

(e) This clause shall have no effect on the Government's rights during the performance of the contract as specified elsewhere herein, including the Governments rights and abilities to request access to or be provided with such records and data for the purpose of conducting any inspections, examinations or audits as set forth in the contract.

ARTICLE H.22. CONSTITUTION DAY

Each educational institution that receives Federal funds for a fiscal year shall hold an educational program on the United States Constitution on September 17 of such year for the students serviced by the educational institution in accordance with Public Law 108-447.

ARTICLE H.23. REVIEW OF MANUSCRIPTS

In order to balance the oversight responsibility of the National Heart, Lung, and Blood Institute (NHLBI) with the authorization provided the contractor by the Rights in Data clause of this contract, the NHLBI has established a process to review manuscripts produced under this contract. Please note that the NHLBI does not require contractors to seek the Institute's approval of manuscripts.

In order to have sufficient time to conduct a meaningful review, please provide to the Institute's Project Officer and Contracting Officer advance notice of intent to submit a manuscript for publication at least 45 days prior to submission to the publisher. The advance notice should briefly describe the plans for publication of the manuscript. Concurrently or as soon as possible following this notice, please provide the manuscript just to the Project Officer.

Any comments from the NHLBI will be provided in writing within 15 days after receipt of the manuscript by the Project Officer. Comments expressed by the NHLBI about the manuscript shall not be a cause for action under the

Disputes clause of the contract by either NHLBI or the contractor, since the NHLBI does not approve manuscripts and draft manuscripts are not contract deliverables.

ARTICLE H.24. ENERGY STAR REQUIREMENTS

Executive Order 13123, "Greening the Government Through Efficient Energy Management" and FAR 23.203 require that when Federal Agencies acquire energy using products, they select, where life-cycle cost-effective, and available, ENERGY STAR® or other energy efficient products. Unless the Contracting Officer determines otherwise, all energy-using products acquired under this contract must be either an ENERGY STAR® or other energy efficient product designated by the Department of Energy's Federal Energy Management Program (FEMP).

For more information about ENERGY STAR® see http://www.energystar.gov/
For more information about FEMP see http://www.eere.energy.gov/

ARTICLE H.25. OMB CLEARANCE

In accordance with HHSAR 352.270-7, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Project Officer and the Contracting Officer has issued written approval to proceed.

ARTICLE H.26. NHLBI LIMITED ACCESS DATA

The National Heart, Lung, and Blood Institute (NHLBI) has supported collection of data from participants in numerous clinical trials and epidemiological studies. These well-characterized population samples represent rare and valuable; scientific resources. In order to take full advantage of such resources and maximize their research value, it is important to that data collected with public funds be made available, under appropriate terms and conditions, to the largest possible number of qualified investigators in a timely manner.

Limited access data will be released under this study. Limited access data refers to study data, with certain deletions and recoding, that are released to requesting institutions and investigators for specific purposes and with certain restrictions and conditions. Limited access data will be made available to the public in accordance with the NHLBI Policy for Distribution of Data http://www.nhlbi.nih.gov/resources/deca/policy_new.htm as revised on June 25, 2005. All changes to the policy are hereby incorporated by reference without further amendment to the contract.

Limited access data is a deliverable under the coordinating center contract for this trial or study, as described in Section C. Description/Specification/Work Statement and/or Section F. Deliveries or Performance of the coordinating center contract.

ARTICLE H. 27. ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) all Electronic and Information Technology (EIT) developed, procured, maintained and/or used under this contract shall be in compliance with the "Electronic and Information Technology Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR Part 1194. The complete text of Section 508 Final Standards can be accessed at http://www.access-board.gov/.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

*THE FOLLOWING **ARTICLE I.1 GENERAL CLAUSE LISTING(S)** WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP*

General Clauses for a Cost-Reimbursement Research and Development Contract

Reg	Clause	Date	Clause Title
FAR	52.202-1	Jul 2004	Definitions (Over $100,000)
FAR	52.203-3	Apr 1984	Gratuities (Over $100,000)
FAR	52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
FAR	52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over $100,000)
FAR	52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
FAR	52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
FAR	52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
FAR	52.203-12	Sep 2005	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
FAR	52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)

FAR	52.204-7	Oct 2003	Central Contractor Registration
FAR	52.209-6	Jan 2005	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
FAR	52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
FAR	52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
FAR	52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
FAR	52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
FAR	52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
FAR	52.215-15	Oct 2004	Pension Adjustments and Asset Reversions
FAR	52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
FAR	52.216-7	Dec 2002	Allowable Cost and Payment
FAR	52.216-8	Mar 1997	Fixed Fee
FAR	52.219-8	May 2004	Utilization of Small Business Concerns (Over $100,000)
FAR	52.219-9	Jul 2005	Small Business Subcontracting Plan (Over $500,000)

FAR	52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
FAR	52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
FAR	52.222-3	Jun 2003	Convict Labor
FAR	52.222-21	Feb 1999	Prohibition of Segregated Facilities
FAR	52.222-26	Apr 2002	Equal Opportunity
FAR	52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
FAR	52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
FAR	52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-14	Aug 2003	Toxic Chemical Release Reporting (Over $100,000)
FAR	52.225-1	Jun 2003	Buy American Act - Supplies
FAR	52.225-13	Mar 2005	Restrictions on Certain Foreign Purchases
FAR	52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
FAR	52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)

FAR	52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
FAR	52.227-14	Jun 1987	Rights in Data - General
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-17	Jun 1996	Interest (Over $100,000)
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-23	Jan 1986	Assignment of Claims
FAR	52.232-25	Oct 2003	Prompt Payment, Alternate I (Feb 2002)
FAR	52.232-33	Oct 2003	Payment by Electronic Funds Transfer--Central Contractor Registration
FAR	52.233-1	Jul 2002	Disputes
FAR	52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy (Over $100,000)

FAR	52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
FAR	52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998)
FAR	52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
FAR	52.244-6	Dec 2004	Subcontracts for Commercial Items
FAR	52.245-5	May 2004	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract)
FAR	52.245-9	Aug 2005	Use and Charges
FAR	52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
FAR	52.249-6	Sep 1996	Termination (Cost-Reimbursement)
FAR	52.249-14	Apr 1984	Excusable Delays
FAR	52.253-1	Jan 1991	Computer Generated Forms
HHSAR	352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
HHSAR	352.216-72	Oct 1990	Additional Cost Principles
HHSAR	352.228-7	Dec 1991	Insurance - Liability to Third Persons
HHSAR	352.232-9	Apr 1984	Withholding of Contract Payments
HHSAR	352.233-70	Apr 1984	Litigation and Claims
HHSAR	352.242-71	Apr 1984	Final Decisions on Audit Findings

HHSAR	352.270-5	Apr 1984	Key Personnel
HHSAR	352.270-6	Jul 1991	Publications and Publicity
HHSAR	352.270-7	Jan 2001	Paperwork Reduction Act

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS:

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal	See Attachment Section at the end of this RFP
Attachment 2:	Proposal Intent Response Sheet	See Attachment Section at the end of this RFP
Attachment 3:	Use of Government-Owned Specimens	See Attachment Section at the end of this RFP

TECHNICAL PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable, and submitted with the Technical Proposal.)

Attachment No.	Title	Location
Attachment 4:	Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Attachment 5:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Attachment 6:	Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
Attachment 7:	Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (formerly Optional Form 310	http://rcb.cancer.gov/rcb-internet/forms/of310.pdf
Attachment 8:	Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf

BUSINESS PROPOSAL ATTACHMENTS: The following attachments must be completed, where applicable, and submitted with the Business Proposal for each twelve month period from January 15, 2007 through January 14, 2009.

Attachment No.	Title	Location
Attachment 9:	Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Attachment 10:	Small Business Subcontracting Plan **[DO NOT SUBMIT with PROPOSAL]**	http://rcb.cancer.gov/rcb-internet/forms/sb-subplan-NHLBI.pdf

Attachment 11:	Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet	http://www.niaid.nih.gov/contract/forms.htm http://ocm.od.nih.gov/contracts/spsh/spshexcl.xls
Attachment 12:	Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Attachment 13:	Certificate of Current Cost or Pricing Data **[DO NOT SUBMIT UNTIL END OF NEGOTIATIONS]**	http://rcb.cancer.gov/rcb-internet/forms/cert-current-cost.pdf
Attachment 14:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf

INFORMATIONAL ATTACHMENTS: (The following Attachments and Reports will become part of any contract resulting from this RFP and will be required during contract performance.)

Attachment No.	Title	Location
Attachment 15:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-1	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 16:	Financial Report of Individual Project/Contract, NIH 2706	http://www.niaid.nih.gov/contract/forms/nih-2706.pdf
Attachment 17:	Instructions for Completing Form NIH 2706	http://www.niaid.nih.gov/contract/forms/instructions2706.pdf
Attachment 18:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

SECTION K can be accessed electronically from the INTERNET at the following address:

http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

COMPLETE SECTION K AND SUBMIT IT AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Provision 52.215-1 (January 2004)]

(a) *Definitions*. As used in this provision--

Discussions are negotiations that occur after selection that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"In writing", *"writing"*, or *"written"* means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time,*" if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--
- (i) The solicitation number;
- (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
- (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals.* (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(*1*) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(*2*) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(*3*) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before

award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) *Restriction on disclosure and use of data.* (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, FINANCIAL information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials

must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be selected exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals to be negotiated.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
(ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.
(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iv) A summary of the rationale for award.
(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.
(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors of the most highly rated proposals. The Contracting Officer may limit the number of proposals selected to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

b. **"JUST IN TIME"**

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information during the initial evaluation of proposals. Certain documents will not longer be required to be submitted with initial proposals, but will be requested at a later stage in the competitive process. Specifically, the travel policy,

the annual FINANCIAL statement, the total compensation plan, and the subcontracting plan, will only be required to be submitted from those offerors selected for negotiations, or the apparent successful offeror. The special procedures for submission of this documentation are set forth in detail below:

Travel Policy. The offeror's (and any proposed subcontractor's) written travel policy shall **not** be submitted with the initial business proposal. All offerors whose proposals have been selected for negotiations will be required to submit a travel policy as a part of their final proposal revision.

Annual Report. The offeror's most recent annual report shall **not** be submitted with the initial business proposal. All offerors whose proposals have been selected for negotiations will be required to submit a copy of their most recent annual report as a part of their final proposal revision.

Total Compensation Plan. The offeror's total compensation plan shall **not** be submitted with the initial business proposal. All offerors whose proposals have been selected for negotiations will be required to submit a total compensation plan as a part of their final proposal revision.

Subcontracting Plan. The offeror's Small Business Subcontracting Plan shall **not** be submitted with the initial business proposal. Only those offerors whose proposals have been selected for negotiations will be required to submit **an acceptable** subcontracting plan before contract award.

c. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.

(2) The small business size standard is 500 employees.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in EVERY solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

d. **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that multiple awards will be made from this solicitation and that the award(s) will be made on or about January 15, 2007.

It is anticipated that the awards from this solicitation will be two-year cost reimbursement-type completion contracts with a period of performance of January 15, 2007 through January 14, 2009, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. **PRE-PROPOSAL CONFERENCE**

A pre-proposal conference will be held for prospective offerors at the Natcher Building on the NIH Bethesda Campus on February 27, 2006, from 1:00-3:00 pm. NHLBI staff will be available to explain the Government's requirements, and to answer any questions you have regarding this solicitation.

The success of this type of conference depends largely on the lead-time available to the Government for research in connection with questions submitted by offerors. Therefore, you are requested to mail or email written questions concerning any areas of uncertainty that, in your opinion, require clarification or correction, in sufficient time to be received on or before February 20, 2006.

Your questions should be submitted to the Contract Specialist, Kim Louth, and the envelope should be marked, "Pre-proposal conference, RFP No. NHLBI-WH-06-09." A set of all questions and answers will be furnished simultaneously to all prospective offerors, whether or not they are in attendance.

Because of space limitations, each prospective offeror shall be limited to a total of two representatives.

Attendance at the pre-proposal conference is recommended; however, attendance is not a prerequisite for proposal submission and will not be considered a factor in proposal evaluation.

f. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

g. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

h. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

i. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors are specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

j. **REFERENCE MATERIALS**

Failure of offerors to examine the reference materials prior to proposal preparation and submission will be at the offeror's risk.

k. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

l. **SERVICE OF PROTEST** (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Betty Nordan, Contracting Officer
Office of Acquisitions
National Heart, Lung, and Blood Institute, NIH
Rockledge Building (RKL II), Room 6222
6107 Rockledge Drive, MSC 7902
BETHESDA MD 20892- 7902

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

m. **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) **Contract Type and General Clauses**

It is contemplated that a cost-reimbursement completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addresses, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD.)

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include

direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS). However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in Part IV, Section M of this RFP.

(7) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurement, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

> **Hard Metric** - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).
>
> **Soft Metric** - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.
>
> **Dual Systems** - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) **Standards for Privacy of Individually Identifiable Health Information**

The Department of Health and Human Services (DHHS) issued final modifications to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities" must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply.

Decisions about the applicability and implementation of the Privacy Rule reside with the contractor and his/her institution. The OCR Web site (http://www.hhs.gov/ocr/) provides information of the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements and contracts can be found at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

Domestic Institutions

For prime or subcontract awards to domestic institutions that possess, use, and/or transfer Select Agents under this contract, the domestic institution must:

- include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.

- comply with 42 CFR part 73, 7 CFR part 331 and/or 9 CFR part 121 at: http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf, as required, before using NIH funds for research involving Select Agents. No NIH funds can be used for research involving Select Agents if the final registration certificate is denied.

Foreign Institutions

For prime or subcontract awards to foreign institutions that possess, use, and/or transfer Select Agents under this contract, the foreign institution must:

- include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.

- when requested during negotiations, provide information satisfactory to the NIAID/NIH that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf for U.S. institutions are in place and will be administered on behalf of all Select Agent work under the resulting contract. The process for making this determination includes inspection of the foreign laboratory facility by an NIAID representative. During this inspection, the foreign institution must

provide the following information: concise summaries of safety, security, and training plans; names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents.

An NIAID-chaired committee of U.S. federal employees (including representatives of NIH grants/contracts and scientific program management, CDC , Department of Justice and other federal intelligence agencies, and Department of State) will ultimately assess the results of the facility inspection, the regulations, policies, and procedures of the foreign institution for equivalence to the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at:

http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf.

The committee will provide recommendations to the DEA Director, NIAID. The DEA Director will make the approval decision and notify the Contracting Officer. The Contracting Officer will inform the prime contractor of the approval status of the foreign institution. No NIH funds can be used for research involving Select Agents at a foreign institution until NIAID grants this approval.

(10) **Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines and for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://ott.od.nih.gov/NewPages/64FR72090.pdf.

(a) **Sharing Research Data**

[Note: The NIH Guide announcement referenced below states that this policy is applicable to "all investigator-initiated applications with direct costs greater than $500,000 in any single year." This is an overall grant policy which requires that an applicant must seek agreement by NIH to accept assignment of their application in advance of the submission date. As such, this policy has not correlation to the contract process, therefore, the threshold is not applicable to contracts. Thus, this article applies to ***any*** *contract that may generate research data.]*

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

[If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. Coordinating Center proposals should describe methods to coordinate the dissemination planning and implementation. The Coordinating Center must include a budget and justification for any additional costs of this collaborative effort.]

(b) **Sharing of Model Organisms for Biomedical Research**

The *NIH Research Tools Policy*, also referred to as Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, December 1999, supports the concept of timely sharing and distribution of research resources. In accordance with NIH Guide Notice NOT-OD-04-042, dated May 7, 2004, and the September 10, 2004 extension of this policy NOT-OD-04-066,the NIH provides further sharing guidance with particular attention on model organisms for biomedical research. Such organisms include, but are not limited to: mammalian models such as the mouse and rat, and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

Offerors must include in their proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, OR provide appropriate reasons why such sharing is restricted or not possible. A reasonable time frame for periodic disposition of material and associated data must be

specified in the proposal. In addition, the plan must address if, or how, offerors will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. At a minimum, the plan should address the following:

- Will material transfers be made with no more restrictive terms than in a Simple Letter Agreement (SLA) (http://ott.od.nih.gov/NewPages/Rtguide_final.html#sla)for the transfer of materials or the Uniform Biological Material Transfer Agreement (UBMTA) (http://ott/od/nh/gov/NewPages/UMTA.pdf)?

- How will inappropriate "reach-through" requirements (as discussed in the NIH Research Tools Policy) on materials transferred be discussed?

- How will technologies remain widely available and accessible to the research community, for example, if any intellectual property rights arise for which a patent application may be filed?

Offerors may request funds in their cost proposal to defray reasonable costs associated with sharing materials or data or transfer of model organisms and associated data to appropriate repositories.

(11) Specific Copyright Provisions Applicable to Software Development and/or Enhancement(s)

Under the provisions of the Rights in Data General clause (52.227-14), contractors must seek permission to establish a copyright for software and associated data generated under a contract. As a general rule, permission is normally granted provided, a paid-up, world-wide, irrevocable, nonexclusive license to the government is provided.

(12) Selection of Offerors

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

(1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being selected for negotiations. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, selection is uncertain. Such communications shall not be used

to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal.

(2) The Contracting Officer will, in concert with program staff, select proposals for negotiation. Oral or written discussions will be conducted with all offerors that have been selected.

NHLBI reserves the right, in special circumstances, to limit the number of proposals included in the selection. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, selected offerors shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The NHLBI reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NHLBI requirements. Synopses of awards exceeding $25,000 will be published in FedBizOpps.

(13) **Small Business Subcontracting Plan**

This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.a. of this RFP.
If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the apparent successful offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, Attachment 10 to this RFP is an example of such a plan.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum

practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(3) A description of the Principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and/or Service Disabled Veteran-Owned Small Business Concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained in the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

(14) **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

(15) **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes.

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) code, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at:

http://www.sba.gov/size

The Department of Commerce website for the annual determination for NAICS codes* is:

http://www.arnet.gov/References/sdbadjustments.htm

**Note: Public Law 103-355 which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.*

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Subsector(s). The applicable authorized NAICS Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An *example* of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Subsector 223

	SDB Percentage of Total Contract Value	**SDB Dollars**
Total Contract Value-$1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
SDB Participation by subcontractors	15%	$150,000

(16) **Salary Rate Limitation in Fiscal Year 2005**

Offerors are advised that pursuant to P.L. 108-447, no NIH Fiscal Year 2005 (October 1, 2004 - September 30, 2005) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 108-447 applies only to Fiscal Year 2005 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 108-447 states in pertinent part:

> "None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I*."

LINK TO EXECUTIVE SCHEDULE SALARIES: http://www.opm.gov/oca/05tables/html/ex.asp
Note to Offerors: *The current Fiscal Year Executive Level I Salary Rate should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award will be required to be in compliance with the current Executive Level I Salary rates.*

(17) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable significant financial interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a significant financial interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(18) **ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

(19) **Past Performance Information**

a) Offerors shall submit the following information as part of their business proposal.

A list of the last five contracts completed during the past three years and all contracts currently in process that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial

concerns. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

Include the following information for each contract or subcontract:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial Code

The offeror shall submit comparable information on all subcontractors proposed to perform a major subcontract under this effort.

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

b) Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

(23) **Electronic and Information Technology Accessibility**

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194), requires that all EIT acquired must ensure that:

a. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

b. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards.

Further information about Section 508 is available via the Internet at http://www.section508.gov.

(24) **Prohibition on Contractor Involvement with Terrorist Activities**

The contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

(25) **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).
b) Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
c) Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).
d) Facsimile Proposals, FAR Clause 52.215-5, (October 1997).
e) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).
f) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
g) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).
j) Identification of Uncompensated Overtime, FAR Clause 52.237-10, (October 1997).

b. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Project Objectives, NIH-1688-1**

The offeror shall insert a completed NIH Form 1688-1, Project Objective, as provided in Section J, Attachments, behind the Title Page of each copy of the proposal, along with the "Government Notice for Handling Proposals." The NIH Form 1688-1 is to be completed as follows:

- For an Institution of Higher Education**:** The form MUST be completed in its entirety.
- For *other* than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank.

The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled "*INSTRUCTIONS."*

b) **Statement of Work**

(1) Objectives
State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach
Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods
Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule
Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

c) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

-The specific items or expertise they will provide.

-Their availability to the project and the amount of time anticipated.

-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (Section M. hereof).

(3) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

(5) **Research Involving Recombinant DNA Molecules (including Human Gene Transfer Research)**

Recombinant DNA Molecules are either 1) molecules that are constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or 2) DNA molecules that result from the replication of those described in 1).

The NIH Guidelines for Research Involving Recombinant DNA Molecules at http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html , and the May 28, 2002 Notice, *Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules*, at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html and any subsequent revisions to the Guide Notice) stipulates biosafety and containment measures for recombinant DNA research and delineates critical, ethical principles and key safety reporting requirements for human gene transfer research (See Appendix M of the NIH Guidelines). These guidelines apply to both basic and clinical research studies.

The Recombinant DNA Advisory Committee (RAC) is charged with the safety of manipulation of genetic material through the use of recombinant DNA techniques. Prior to beginning any clinical trials involving the transfer of recombinant DNA to humans, the trial must be registered with the RAC. If this contract involves new protocols that contain unique and//or novel issues, the RAC must discuss them in a public forum and then the Institutional Biosafety Committee (IBC), the Institutional Review Board (IRB), and the project officer and contracting officer must approve the protocol prior to the start of the research.

Failure to comply with these requirements may result in suspension, limitation, or termination of NIH funding for any work related to Recombinant DNA Research or a requirement for the contracting officer's prior approval of any or all Recombinant DNA projects under any contract awarded from this solicitation. This includes the requirements of the Standing Institutional Biosafety Committee (IBC) (See http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm.)

As specified in Appendix M-1-C-4 of the NIH Guidelines, any serious adverse event must be reported immediately to the IRB, the IBC, the Office for Human Research Protections (if applicable), and the NIH Office for Biotechnology Activities (OBA), followed by the filing of a written report with each office/group and copies to the project officer and contracting officer.

http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm#_Toc7255836

(6) Human Embryonic Germ Cell (HEGC) Research

1. Guidelines.

   Research use of human embryonic germ cells derived from fetal tissue with Federal funds requires review of compliance with the *NIH Guidelines for Research Using Human Pluripotent Stem Cells*

   (http://stemcells.nih.gov/policy/guidelines.asp) (only the information regarding human embryonic germ cells is relevant). Embryonic germ cells are pluripotent stem cells derived from human embryos. See *NIH Guide for Grants and Contracts Notice* NOT-OD-02-049, requiring that offerors/contractors submit certain documents to the Human Pluripotent Stem Cell Review Group

(HPSCRG), which will be reviewed in a public meeting. Research using human embryonic germ cells may not be performed prior to approval by the HPSCRG.

All offerors should read the "NIH Guidelines" (http://stemcells.nih.gov/policy/guidelines.asp) if they either: (1) propose to respond to the Statement of Work requirements by conducting research that uses human embryonic germ cells or, (2) are responding to a Statement of Work that requires the use of human embryonic germ cells.

Offerors may obtain copies of these Guidelines from the website above or from the contact person listed in this solicitation.

22. Procedure for Required Review by Human Pluripotent Stem Cell Review Group (HPSCRG)

If the offeror intends to fulfill the requirements of the Statement of Work by performing research using human embryonic germ cells, it must so state in its proposal.

If the offeror's proposal includes research using human embryonic germ cells and it receives a contract award, the contractor may not perform any research using these human embryonic germ cells until the Human Pluripotent Stem Cell Review Group (HPSCRG) has reviewed and approved the documentation furnished as prescribed in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html) and the contracting officer has notified the contractor of the approval in writing.

This documentation will be forwarded for review and approval to the HPSCRG.

If the HPSCRG disapproves the documentation presented by the contractor, the Contracting Officer may elect to either terminate the contract in accordance with the Termination for Convenience clause of the contract OR determine not to exercise subsequent option(s) as appropriate based the terms of the specific contract. Otherwise, when the HPSCRG approves the documentation, the contracting officer will notify the contractor in writing that research using the human embryonic germ cells may commence.

Research involving the use of human embryonic germ cells shall not be conducted under the contract until the HPSCRG review and approval have been obtained, and the contracting officer has provided written notice of such approval to the contractor.

(7) **Human Embryonic Stem Cell (HESC) Research**

On August 9, 2001, the President announced the criteria that must be met for Federal funds to be used for research on existing human embryonic stem cell lines. These criteria were subsequently published by the NIH at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. The following eligibility criteria must be met:

1. The derivation process (which commences with the removal of the inner cell mass from the blastocyst) must have already been initiated prior to August 9, 2001;

2. Prior to August 9, 2001, the embryo from which the stem cell line was derived no longer had the possibility of development as a human being;
3. The stem cells must have been derived from an embryo that was created for reproductive purposes;
4. The embryo was no longer needed for these purposes;
5. Informed consent must have been obtained for the donation of the embryo;
6. No FINANCIAL inducements were provided for the donation of the embryo.

To facilitate research using human embryonic stem cells, the NIH has established a Human Embryonic Stem
Cell Registry ("the NIH Registry") that lists the human embryonic stem cells that meet the eligibility criteria. This registry is available at: http://stemcells.nih.gov/registry/.

Research involving the derivation of new stem cells from human embryos or the use of human embryonic stem cells that are not listed on the NIH Human Embryonic Stem Cell Registry may not be conducted with Federal funding.

If a particular human embryonic stem cell line has not been required by the Statement of Work, an offeror proposing research involving human embryonic stem cells must cite a human embryonic stem cell line that is listed in the NIH Registry in its proposal.

c. BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price for each 12-month period during the period of performance. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Proposal Cover Sheet

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name, telephone number, and email address of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Total proposed cost and/or price; profit or fee ; and total for each 12-month period;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and

9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

(3) **Information Other than Cost or Pricing Data**

a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

b) The information submitted shall be at the level of detail described below.

1. **Direct Labor**

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. **Materials**

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. **Subcontracted Items**

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $550,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. **Raw Materials**

Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. **Purchased Parts**

Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**

Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

7. **Indirect Costs**

Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. **Special Equipment**

If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. **Travel**

Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. **Other Costs**

List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

(4) **Cost and Pricing Data**

1. **General Instructions**

A. You must provide the following information on the first page of your pricing proposal:

(1) Solicitation, contract, and/or modification number;
(2) Name and address of offeror;
(3) Name and telephone number of point of contact;
(4) Name of contract administration office (if available);
(5) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
(6) Proposed cost; profit or fee; and total;
(7) Whether you will require the use of Government property in the performance of the

contract, and, if so, what property (see Attachment 3 at end of this RFP);

(8) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;

(9) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;

(10) Date of submission; and

(11) Name, title and signature of authorized representative.

B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including--

(1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and

(2) The nature and amount of any contingencies included in the proposed price.

D. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.

F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.

G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

2. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

A. **Materials and services**. Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.

(1) *Adequate Price Competition*. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).

(2) *All Other*. Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are

generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

B. **Direct Labor**. Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.

C. **Indirect Costs**. Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

D. **Other Costs**. List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

E. **Royalties**. If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

(1) Name and address of licensor.
(2) Date of license agreement.
(3) Patent numbers.
(4) Patent application serial numbers, or other basis on which the royalty is payable.
(5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
(6) Percentage or dollar rate of royalty per unit.
(7) Unit price of contract item.
(8) Number of units.
(9) Total dollar amount of royalties.
(10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).

F. **Facilities Capital Cost of Money**. When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

3. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (Section J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition,

summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

4. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

5. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

NOTE: Data substantiating the costs or prices proposed (i.e. payroll documentation, vendor quotes, invoice price, etc.) shall not be submitted with the initial proposal. This information will be requested from the offeror during the negotiation process. The initial proposal need only indicate from what source the proposed costs and prices are substantiated.

(5) **Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data** [FAR Clause 52.215-20 (October 1997)]

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or

describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(6) **Total Compensation Plan - Instructions**

[NOTE: This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.a. of this RFP.]

a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors whose proposals have been selected for negotiations will be required to submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total

compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

(7) **Total Compensation Plan - Evaluation**

a) **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

b) **Cost (Professional Compensation)**

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

c) **Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

d) **Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

(8) **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

Performance history is defined as meeting contract objectives within delivery and cost schedules on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(9) **Other Administrative Data**

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) **Royalties**

The offeror shall furnish information concerning royalties which are anticipated to be paid in connection with performance of work under the proposed contract.

c)_ Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38, (May 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's

official authorized to provide this information.

(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.

(5) The offeror's account number and the type of account (checking, savings, or lockbox).

(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.

(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

d) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

e) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

f) **Facilities Capital Cost of Money**, FAR 52.215-16, (June 2003)

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(10) **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following web site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

(11) **Proposer's Annual Financial Report**

[NOTE: This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.a. of this RFP.]

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(12) **Representations and Certifications**

One copy of the Representations and Certifications referenced as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(13) **Travel Costs/Travel Policy**

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

[NOTE: This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.a. of this RFP.]

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

(14) **Certification of Visas for Non-U.S. Citizens**

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its outlying areas, then the offeror must indicate in the proposal that these individuals have the required visas.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

The primary basis for selecting proposals submitted in response to a BAA shall be three factors: technical excellence, importance to agency programs, and fund availability. The technical evaluation of proposals will be conducted through a peer review process in accordance with established criteria. The technical evaluation criteria will be weighted as follows:

Technical Evaluation Factors	**Weight**
SCIENTIFIC AND TECHNICAL APPROACH	40 points

Extent to which proposed research plan accomplishes the scientific goals set out in this solicitation, and extent to which adequately tested, appropriate technologies and approaches are employed. Relevance of plan to advancing scientific knowledge and public health. Appropriateness of the milestones and timelines of the plan, and overall technical feasibility of the proposed plan.

ADEQUACY OF THE TECHNICAL APPROACH	20 points

Adequacy of the proposed research plan in regard to parsimonious use of samples and consideration of overlap with existing funded research in WHI

OFFEROR'S CAPABILITIES	20 points

Capabilities, related experience, facilities, and techniques, which the offeror possesses (and which are considered integral factors) for achieving the objective(s).

QUALIFICATIONS, CAPABILITIES EXPERIENCE, AND AVAILABILITY OF PROPOSED KEY PERSONNEL	20 points

Documented training, experience, expertise, and availability of the Principal Investigator for planning and directing the investigation. Documented training, experience, and availability of all personnel in conducting the proposed procedures.

NHLBI program and administrative staff will determine importance to agency programs and availability of funds. In addition, past performance of the offeror and the extent of small disadvantaged business concerns in performance of the program will also be evaluated in accordance with FAR 15.304.

2. PAST PERFORMANCE FACTOR

An evaluation of offeror's past performance information will be conducted subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal would not be selected for award based on the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The Government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechnaical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgement by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

3. **EVALUATION OF DATA SHARING PLAN**

The offeror's plan for the sharing of final research data, or, if data sharing is not possible, the offeror's documentation of its inability to share research data, shall be assessed for appropriateness and adequacy.

4. **EVALUATION OF FOREIGN CURRENCY OFFERS**, FAR 52.225-17, (FEBRUARY 2000)

If the Government receives offers in more than one currency, the Government will evaluate offers by converting the foreign currency to United States currency using exchange rates in effect on the date specified for receipt of proposal revisions.

5. **EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before selection of proposals for award is completed. Evaluation of SDB participation will be assessed based on

consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

(a) Extent to which SDB concerns are specifically identified
(b) Extent of commitment to use SDB concerns
(c) Complexity and variety of the work SDB concerns are to perform
(d) Realism of the proposal
(e) Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
(f) Extent of participation of SDB concerns in terms of the value of the total acquisition.

6. **SUBCONTRACTING PROGRAM EVALUATION CRITERIA**

The offeror's proposed Small Business Subcontracting Plan will be evaluated to determine whether it represents the maximum practicable opportunity for subcontracting. Because the offeror's record of previous performance in carrying out the intent of the subcontracting program will be considered, each offeror is encouraged to submit subcontracting plans and documentation that demonstrates their prior corporate support for small, small disadvantaged, women-owned small, HUBZone small, veteran-owned small, and service-disabled veteran-owned small business suppliers.

Note to Offerors: The Small Business Subcontracting Plan need NOT be submitted with the original proposal . Subcontracting plans will be required only from those Offerors selected for negotiations.

SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP

The following pages include Attachments 1-3 to this RFP as specified in SECTION J - List of Attachments

PACKAGING AND DELIVERY OF PROPOSAL

DUE DATE: 4:00 p.m. local time on April 7, 2006

Proposals not received at the place and time specified in the solicitation will be considered late and will handled in accordance with HHSAR 352.215-70, entitled "Late Proposals and Revisions" located in section L.1.m of this solicitation. Your proposal shall be organized as specified in Section L.2., "Instructions to Offerors." Shipment and marking shall be as indicated below.

EXTERNAL PACKAGE MARKING: In addition to the address cited below, mark each package as follows:

"RFP NO. NHLBI-WH-06-09
Toward Maximizing the Scientific Value of the
Biologic Specimens of the Women's Health Initiative"

"TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

NUMBER OF COPIES:
Technical Proposal: Original and Thirty (**30**) Copies
Business Proposal: Original and Four (**4**) Copies

IF HAND-DELIVERED/DELIVERY SERVICE: IF USING U.S. POSTAL SERVICE:

Review Branch, Division of Extramural Activities
National Heart, Lung, and Blood Institute
Rockledge 2, Room 7091
6701 ROCKLEDGE DR MSC 7924
BETHESDA, MD 20817

Review Branch, Division of Extramural Activities
National Heart, Lung, and Blood Institute
Rockledge 2, Room 7091
6701 ROCKLEDGE DR MSC 7924
BETHESDA, MD 20892-7924

*****THE ORIGINALS MUST BE READILY ACCESSIBLE FOR DATE STAMPING PURPOSES.

Attachment 1

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NHLBI-WH-06-09

TITLE OF RFP: "Towards Maximizing the Scientific Value of the Biologic Specimens from the Women's Health Initiative"

If you intend to submit a proposal, please furnish the information requested below and return this page by **March 10, 2006**. Your expression of intent is not binding, but will assist us in planning for proposal evaluation.

COMPANY/INSTITUTION NAME:

ADDRESS:

PROJECT DIRECTOR'S/PRINCIPAL INVESTIGATOR'S NAME:

PROJECT DIRECTOR'S/PRINCIPAL INVESTIGATOR'S TITLE:

EMAIL ADDRESS:

TELEPHONE NUMBER:

COLLABORATING INSTITUTIONS AND INVESTIGATORS:

(for each subcontractor or consultant, provide the name of the institution, project director's name, and title)

RETURN TO:

Kim Louth, Contract Specialist
Office of Acquisitions
NIH, NHLBI, Room 6215
6701 ROCKLEDGE DR MSC 7924
BETHESDA MD 20892-7902
FAX (301) 480-3338
klouth@nhlbi.nih.gov

Attachment 2

USE OF GOVERNMENT-OWNED SPECIMENS

Offeror hereby certifies that all government-owned specimens, tissue, or blood samples provided for the performance of the awarded contract will be used for no other purpose than that stated in the proposal.

Offeror **Date**

Attachment 3